# Critical Appraisal of Drug Promotional Literature

All informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and / or use of medicinal drugs is termed as ***drug promotion***. It has an important bearing on the rational use of drugs, price-control mechanisms, manufacture, availability and the use of essential drugs and the cost of Healthcare, thus making it a Central Public Health issue.

The clinicians get information about new drugs through various sources. one of the most important sources of drug information to the clinicians is the promotional literature provided by the pharmaceutical companies. The information is in the form of verbal presentations by medical representatives in the physician’s clinics for the advertisements in the journals. verbal presentations by medical representatives may be more powerful as they are readily available and many a times, they are the only source on which physician depend for updating their knowledge.

Drug promotional literature is a major marketing technique in the pharmaceutical industry and busy physicians may at times rely on these promotional literatures. It is a source of education for most busy and practicing physicians. Drug promotion influences physicians, especially those in training. Hence, the information provided in this promotional literature should be factual, evidence-based, unambiguous and balanced. Unfortunately, most of the times, these literatures are neither factual nor evidence-based. The majority of the advertisements or based on studies of poor methodological quality. Inaccurate and incomplete information is made palatable when given along with gifts.

The information provided may be inaccurate and inappropriate which may lead to inappropriate prescriptions resulting in increased Healthcare costs without much benefit to the patients. Every physician should be equipped with the necessary skills, patience and knowledge to critically evaluate the information provided in the drug promotional literature. Active approach by Doctors can transform it into a useful and accurate source of information. A new drug should be selected on the basis of clinical relevance, efficacy, safety, tolerability and cost compared to the already established drug.

**Codes which deal with the promotion of drugs:**

* International Federation of pharmaceutical manufacturers (IFPMA) code of pharmaceutical marketing practices
* WHO criteria for medicinal drug promotion
* Self-regulatory code of pharmaceutical marketing practices- prepared by organization of Pharmaceutical producers of India (OPPI)
* International code on Pharmaceuticals- prepared by health action International (HAI)
* The drug and magic remedies (objectionable advertisement) Act and rules

**What do the regulations say?**

* Manufacturers for traders cannot promote their product for indications that are not listed in the approved product information.
* They cannot promote their products over telephones and the promotional material must not be marked urgent attention.
* Unsolicited reprint of journal articles must be consistent with the product information on the word safe cannot be used unless it is substantiated.
* Committees are set up the monitor drug promotion. The regional committee are located at Chandigarh, Mumbai, New Delhi and Chennai.
* The central ethics committee collect information on unethical advertising practices of Pharmaceutical manufacturers and forwards complaints to the drugs control authority.
* The drugs control authority is empowered to take necessary legal steps on this unethical promotion (drugs and magic remedies act [ 5] for objectionable advertisement, 1954, clause 4).

**How to appraise the drug promotional literature**

**General assessment**: promotional material is made attractive and catches our eye due to its design, colors and image. It creates mental links between the drug, indication and the image that establishes in the prescriber’s Mind by passing his / her critical appraisal defenses. The impact of this influence is further intensified by repetition i.e., repeated exposures build small effects which create a long-term impact. When a patient presents his / her case, the prescriber will think of the most powerfully promoter drugs first. The physician must look beyond these distractions for complete information about the drug.

Sometimes key issues like ADR’s, contraindications and precautions may be entirely omitted or presented in very fine print.

Presentation of the words- size, Color, contrast may be misleading.

E.g.: **Benefits** Disadvantages

Here, although the words are the same point size, the color and contrast make the word ‘benefits’ much more noticeable than the word disadvantages.

**Drug name size:** Letters of the generic names should be at least half as large (actual size, not the font size) of the the proprietary names. The generic names should have the same prominence as that of proprietary names (in terms of typography, layout, contrast and other printing features).

**Pictures:** The type and relevance of the pictures should also be assessed.

**Scientific table and graphs**

*Pseudograph: graphical presentation without proper axes, labelling legend*

**An area used for a brief description of the information (abbreviated prescribing information):**

The abbreviated prescribing information should include unapproved indication or indications for use together with the dosage and the method of use contraindications, precautions and adverse effect.

**Claims made in promotional literature**: check the claims made in the promotional literature. Claims are made about the efficacy, safety, cost, convenience, pharmacokinetic properties. some examples of extravagant emotional claims are first of its kind, flavored, packaging characteristics, etc.

The promotional claims should be current, accurate, balanced and not misleading, either directly or by implication or omission.

**Supporting scientific evidence (references):**

-Check whether there are sufficient references to substantiate the claims made by the new products.

-Design and methodology of the study should also be checked. Clinicians should be equipped to identify studies of poor methodological quality

-Retrievability and validity of references should be checked as well.

**Types of promotional literature:**

* **Printed promotional material**: flip-charts, brochures, leaflets, journal advertisements etc.,
* **Reminder advertisements**
* **Electronic material including audio-visuals**
* **Advertisements to the general public printed promotional material:** They should contain all the elements as per WHO criteria, including 'abbreviated prescribing information'.

**WHO criteria for promotional literature:**

1. The name(s) of the active ingredient(s) using other international nonproprietary names (INN) or the approved generic name of the drug.
2. The brand name.
3. **Pharmacological data**: a brief description of the pharmacological effects and the mechanism of action.
4. **clinical information:**

**-Indications**: whenever appropriate, simple Diagnostic criteria should be provided.

-**Dosage regimen and the relevant pharmacokinetic data**:

(a)Average and range for adults and children;

(b) dosing interval;

(c) average duration of treatment;

(d) special situations, e.g.: renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage.

-Contraindications

-Precautions and warnings (reference to pregnancy, lactation, etc.,)

-Adverse effects (quantify by category, if possible)

-Drug interactions (include only if clinically relevant; drugs used for self-medication to be included)

-**Overdosage**:

* Brief clinical description of symptoms
* Non-drug treatment and supportive therapy
* Specific antidotes

**5.Pharmaceutical information:**

(a) Dosage form

(b) Strength of dosage form

(c) Excipients

(d) Storage conditions and shelf life (expiry date)

(e) Pack sizes

(f) Description of the product and package

(g) Legal category (narcotic or other controlled drug, prescription or non-prescription)

(h) Name and address of manufacturer(s) and importer(s)

**6.Reference to scientific literature as appropriate.**

**Reminder advertisements:** A reminder advertisement is defined as a short advertisement containing just the name of the product and a simple statement of indications to designate the therapeutic category of the product. For reminder advertisements, abbreviated prescribing information may be omitted. They ought to include at least the brand name, the international non- proprietary name for the approved generic name, the name of each active ingredient, and the name and address of the manufacturer or the distributor for the purpose of receiving for the information. These are exempted from the risk disclosure requirements as they were designed to remind physicians of a product's availability (physicians presumably know both the name of a product and its use). Reminders are not allowed for products with serious warnings (‘black box’ warnings) in their labelling.

**Electronic materials, including audio-visuals:**

* The criteria should be similar to the printed materials.
* The Identity of the pharmaceutical company and of the intended audience should be readily Apparent.
* Content and presentation should be appropriate for the intended audience.
* Information should comply with the drugs and magic remedies act.

**Advertisement to the general public:**

* The drug and magic remedies (objectionable advertisement) Act and rules mention a list of ailments for which no advertising is permitted. It also prohibits a false or misleading advertisement.
* Currently, there is no specific law which prohibits the advertising of prescription drugs.
* Of late, the government is planning to impose a total ban on the advertisement of prescription drugs to the general public.
* Scheduled narcotic and psychotropic drugs should not be advertised to the general public.
* Drug advertisements should not be directed at children.
* Advertisements should help people make rational decisions on the use of drugs which are legally available without any prescriptions.
* They should not take undue advantage of peoples concern about their health.
* Advertisements may claim that the drug can cure prevent or relieve an ailment only this can be substantiated.
* They should also indicate, where applicable, appropriate limitations to the use of the drug.
* When lay-language is used, the information should be consistent with the approved scientific data sheet.
* Language which brings about fear of distance should not be used.
* **The advertisements should contain:**

1. The name(s) of the active ingredient(s) using **either** the INN or the approved generic name of the drug.
2. The brand name.
3. Major indication(s) for use.
4. Major precautions, contraindications and warnings.
5. Name and address of the manufacturer or the distributor.
6. Information on price should be accurately and honestly portrait to the consumer.